

K811959 TANDEM PAP KIT - (PARTS I & II)Sep 1, 1981
54 days to decisionK811959 · Product code: **JFH** · Chemistry
Source: <https://www.510kdatabase.net/k811959/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Acid Phosphatase (prostatic), Tartrate Inhibited (JFH)
Date received	Jul 9, 1981
Decision date	Sep 1, 1981
Days to decision	54 days
Third-party review	No

APPLICANT

Company	Hybritech, Inc.
Location	Mchenry, IL, US
510(k) history	63 submissions · 63 cleared · 1981-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k811959/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 30, 2026